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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,788	09/17/2003	Yeung Siu Yu	LFS0097USDIV	9001
27777	7590	12/14/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			12/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/666,788	Applicant(s) YU ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 October 2007 has been entered.

***Status of the Claims***

2. This action is in response to papers filed 5 October 2007 in which claims 21 and 26 were amended to define the surface modification layer as made up of "identical" molecules. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 26 March 2007, not reiterated below, are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Claims 21-26 are under prosecution.

***Information Disclosure Statement***

3. The references listed on the 1449 have been considered as indicated on the form. Those references lined through have not been considered because they are non-English Language documents. The English-Language equivalents have been considered as indicated on the 1449.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruger et al (U.S. Patent No. 5,834,224, issued 10 November 1998) in view of Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997).

Regarding Claim 21, Ruger et al teach a similar device comprising a reaction zone having a homogeneous surface monolayer of SAM (Column 2, lines 33-45) having a first sulfhydryl end group (i.e. anchor group, Column 3, lines 20-28) and a second sulfonate end group (e.g. charged group, Column 4, lines 38-43) separated by an alkyl linker (e.g. spacer, Column 5, lines 11-24) and a redox reagent system comprising an enzyme and a mediator (Column 3, line 62-Column 4, line 13). Ruger et al further teach the monolayer "consists of a single type of molecule" (Column 3, lines 28-37). Ruger et al do not teach the test strip in kit format further comprising means for obtaining a sample and analyte standard.

Bamdad teaches a kit (Column 5, lines 12-20) comprising a similar electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and Example 17, Column 44, line 60-Column 45, line 30) and a means for

obtaining a sample (e.g. inlet #93) and an analyte standard (e.g. positive and negative controls, Column 32, lines 14-17). Bamdad teaches the SAM comprises a functional group that adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) and a minor component for biomolecule attachment (Column 16, lines 12-15). Bamdad further defines the monolayer a single type of SAM (Column 5, lines 12-20) but does not teach the monolayer is made up of identical molecules having a sulfonate end group for biomolecule attachment.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the identical molecules and second end group of Ruger et al to the test strip of Bamdad. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teaching of Ruger et al wherein the sulfonate is the preferred end group for enzyme coupling (Column 4, lines 38-43).

Additionally, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the kit format, sample obtaining means and standards of Bamdad to the test strip of Ruger et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit providing the means for detecting low-affinity targets from a sample within a reaction chamber wherein all components are combined for use into a kit format (Column 5, lines 12-20 and Column 32, lines 14-17).

Regarding Claim 22, Bamdad teaches the kit wherein the analyte is glucose i.e. glucose test meter (Column 23, lines 20-60) and Ruger et al also teach the system wherein the analyte is glucose (Abstract).

Regarding Claim 23, Bamdad teaches the kit wherein the sample is blood (e.g. Column 25, line 67)

Regarding Claim 25, Bamdad teaches the kit comprising a test strip as described above and further teaches test strip is present in an automated instrument designed to work with test strips (Column 23, lines 20-60).

Regarding Claim 26, Bamdad teaches the test strip as described above wherein the test strip is present in an automated instrument designed to work with test strips (Column 23, lines 20-60). Furthermore, the courts have stated that broadly providing an automatic or mechanical means to replace a manual activity that accomplished the same result is not sufficient to distinguish over the prior art (see: *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)) (see MPEP 2144.04 III).

### **Response to Arguments**

6. Applicant asserts that Bamdad teaches a mixed monolayer and Ruger teaches a diluted monolayer, but neither teach the modification layer of identical molecules as instantly claimed. The assertion is noted but not found persuasive to overcome the above rejection. While Ruger does teach the preferred embodiment had diluent molecules, the reference also teaches the monolayer "consists of a single type of molecule" (Column 3, lines 28-37). Therefore, the asserted novelty is obvious in view of the combined references.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) and Ruger et al (U.S. Patent No. 5,834,224, issued 10 November 1998) as applied to Claim 21 above and further in view of Blackman (U.S. Patent No. 4,813,538 issued 21 March 1989).

Regarding Claim 24, Bamdad and Ruger et al disclose the kit of Claim 21 as described above wherein the sample is blood (Column 25, line 67) and the analyte is glucose (Column 23, lines 20-60) but they do not teach the kit comprising a lance for obtaining the blood sample. However, kits comprising a lance for obtaining blood samples were well known in the art at the time the claimed invention was made as taught by Blackman who teaches the lance provides a reusable means of obtaining blood samples (Abstract, Column 5, lines 6-9 and Claims 13-15).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the kit of Bamdad and Ruger et al by including the lance of Blackman.

One of ordinary skill in the art would have been motivated to do so based on the economy and convenience of reusable components as taught by Blackman (Column 2, lines 14-17).

#### **Response to Arguments**

8. Applicant argues that Blackman does not cure the deficiencies of Ruger and Bamdad. The argument has been considered but is not found persuasive because as stated above, the cited references are not deemed deficient.

#### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 26 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,577 in view of Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) or Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999).

Instant Claim 26 and patent Claim 1 are both drawn to test strips. The claims differ in that the test strip of instant Claim 26 is within a "system" comprising an "automated instrument". Test strips within systems comprising automated instruments were well known in the art at the time the claimed invention was made as taught by both Bamdad and Backhaus. Bamdad teaches the test strip as described above wherein the test strip is present in an automated instrument designed to work with test strips (Columns 23-24, e.g. network analyzer, Column 24, lines 43-56) and Backhaus et al teach the similar test strip is present in an automated instrument which is designed to work with test strips e.g. spectrophotometer (Column 6, lines 3-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the automated instrument of Bamdad and Backhaus to the patent test strip for the obvious benefit of networked analysis of reaction on the test strip as taught by Bamdad (Column 24, lines 43-56).

Furthermore, the courts have stated that broadly providing an automatic or mechanical means to replace a manual activity that accomplished the same result is not sufficient to distinguish over the prior art (see: *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)) (see MPEP 2144.04 III). Therefore, the combining the patent test strip with an automated instrument would not distinguish the combination over the patent test strip.

#### **Response to Comments**

Applicant acknowledges the above obviousness-type double patenting rejection and states that a terminal disclaimer will be submitted upon indication of allowable subject matter. The rejection is maintained.

#### **Conclusion**

11. No claim is allowed.



12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

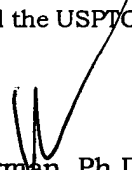
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Art Unit: 1634  
December 12, 2007